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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/486,839	03/01/00	ACHARI	R 719-75-PCT/U

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GERALD T. BODNER
HOFFMANN & BARON LLP
6900 JERICHO TURNPIKE
SYOSSET NY 11791

EXAMINER	
JIANG, S	
ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/486,839	ACHARI ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

This application is a 371 of PCT/US98/18953.

This application claims priority to provisional application Serial No. 60/058,651.

Claim Objection

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition employed in a method will not further limit claims drawn to the method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5, 7, 14, 17-18, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "said concentration " in claims 3-4 and 17-18 renders the claim indefinite. The expression " said concentration " is not defined by the claim. The expression " said concentration " is unclear as to the said concentration of which component in the formulation herein.

The expression "a chemically modified equivalent" or " chemically modified equivalents" in claims 7 and 14 renders claims 7 and 14 indefinite. The expression "a chemically modified equivalent" or " chemically modified equivalents" is not defined by the claims. Therefore, the scope of claims is indefinite as to chemically modified equivalents in the formulation encompassed thereby.

The expression "scopolamine free base plasma concentration is achieved within about 5 minutes" in claim 21 renders the claim indefinite. The expression "scopolamine free base plasma concentration is achieved..." is not defined by the claim. The "scopolamine free base plasma concentration is achieved..." is unclear as to how much scopolamine free base in plasma within about 5 minutes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (PTO-1449 submitted August 1, 2000) in view of Osol et al. (PTO-1449 submitted August 1, 2000).

Keith discloses that an intranasal formulation comprising scopolamine hydrochloride in a pharmaceutically acceptable carrier, an aqueous solution containing

ethanol is useful in a method of preventing and/or treating motion sickness such as nausea and/or vomiting. See abstract, Examples I-XII, and claims 1-6. Keith also discloses that the intranasal formulation therein provides quick relief from motion sickness and the onset of effect is within ten minutes. See page 2 lines 3-4, page 3 Example II, and page 4 Example IV.

The prior art does not expressly disclose the employment of polyvinyl alcohol in combination with one or more additional gelling agents or bioadhesives such as alginates, gums, and starches in the instant intranasal formulation and method for the treatment of motion sickness. The prior art does also not expressly disclose that the pH value of the instant intranasal formulation is below about 4 or 3.5, and the concentration of the buffer salt in the instant intranasal formulation is below about 200 mM or 100 mM or 50 mM. The prior art does not further expressly disclose the employment of the particular salt of scopolamine, hydrobromide and thickening agents and surfactants in the formulation herein. The prior art does not further expressly disclose that the instant intranasal formulation effects within about 5 minutes.

Osol et al. teaches that polyvinyl alcohol is a well known pharmaceutically acceptable gelling agent which may be used in combination with one or more additional gelling agents. Osol et al. also teaches that alginates, gums, and starches are also well known pharmaceutically acceptable gelling agents. See page 1242 and 1244.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ polyvinyl alcohol in combination with one or more additional gelling agents or bioadhesives such as alginates, gums, and starches in the

instant intranasal formulation and method for the treatment of nausea and/or vomiting associated with motion sickness, and to employ the particular salt of scopolamine, hydrobromide, and to further employ thickening agents and surfactants in the formulation herein, and to optimize the pH of the instant intranasal formulation to below about 4 or 3.5 and the concentration of the buffer salt in the instant intranasal formulation to below about 200 mM or 100 mM or 50 mM.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ polyvinyl alcohol in combination with one or more additional gelling agents or bioadhesives such as alginates, gums, and starches in the instant intranasal formulation and method for the treatment of nausea and/or vomiting associated with motion sickness since polyvinyl alcohol is a well known pharmaceutically acceptable gelling agent which may be used in combination with one or more other well known pharmaceutically acceptable gelling agents such as alginates, gums, and starches according to Osol et al. Moreover, the determination or optimization of pharmaceutically acceptable carriers is considered well within the skill of artisan. Additionally, one of ordinary skill in the art would have been motivated to employ the particular salt of scopolamine, hydrobromide, and to further employ thickening agents and surfactants in the formulation herein because the determination of well known pharmaceutical acceptable salts in a composition and the employment of well known thickening agents and surfactants in the pharmaceutical art are considered well within the skill of artisan. Further, one of ordinary skill in the art would have been motivated to optimize the pH of the instant intranasal formulation to below about 4 or

3.5, and to optimize the concentration of the buffer salt in the instant intranasal formulation to below about 200 mM or 100 mM or 50 mM because the optimization of the pH and the concentration of the buffer salt of the instant intranasal formulation are considered well within the skill of artisan. The onset of effective time of an intranasal composition would be expected by one of ordinary skill in the art.

Since all composition components herein are known, it is considered prima facie obvious to combine them into a single composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
May 30, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600